

# Fecal Microbiota Spores, Live - jslm (REBYOTA)

## Criteria for Use Updated Feb 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES. The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov> for further information.*

**Exclusion Criteria** *If the answer to ANY item below is met, then the patient should NOT receive REBYOTA.*

- History of severe allergic reactions to any component of REBYOTA
- Asymptomatic *Clostridioides difficile* colonization
- Is likely to require antibiotic therapy for a condition other than *Clostridioides difficile* infection (CDI) OR planned surgery requiring perioperative antibiotics within 8 weeks after treatment
- Severe immunosuppression<sup>1</sup>

**Inclusion Criteria** *The answers to ALL OF THE FOLLOWING must be fulfilled in order to meet criteria.*

- At least 2<sup>nd</sup> episode of recurrent CDI (3<sup>rd</sup> episode overall) in the previous 12 months (defined as CDI recurring within 8 weeks of completion of standard CDI treatment)
- Successful treatment of current episode of CDI with standard of care CDI antibiotics (fidaxomicin or PO vancomycin)
- Within 1-3 days after completion of standard of care CDI antibiotics (fidaxomicin or PO vancomycin)
- At least one episode of CDI was treated with fidaxomicin, unless not tolerated or contraindicated

### Dosage and Administration

Administer a single dose of 150 mL rectally as an enema, 24-72 hours after the last dose of antibiotics for CDI

### Supplemental Information

- <sup>1</sup> severe immunosuppression includes neutropenia, early post solid organ or peripheral blood stem cell transplant or equivalent degree of immunosuppression from other diseases or medications
- REB has not been studied and is not FDA indicated for an initial episode of CDI
  - REBYOTA should be avoided in patients who are immunocompromised. Further data is required before making a recommendation in this population.

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